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| APPLICATION NO.    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--------------------|-------------|----------------------|----------------------|------------------|
| 10/022,607         | 12/17/2001  | Ni Ding              | 10177-103            | 5308             |
| 20583              | 7590        | 06/06/2005           | EXAMINER             |                  |
| JONES DAY          |             |                      | PRONE, CHRISTOPHER D |                  |
| 222 EAST 41ST ST   |             |                      | ART UNIT             |                  |
| NEW YORK, NY 10017 |             |                      | PAPER NUMBER         |                  |

3738

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |   |                                    |  |
|------------------------------|---|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/022,607    | <b>Applicant(s)</b><br>DING ET AL. |  |
|                              | <b>Examiner</b><br>Christopher D. Prone | <b>Art Unit</b><br>3738            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 8, 9-12, 14, 17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Burton (EP 0565542).

With reference to Figure 2 Dayton discloses an expandable prefabricated stent 11 that is later coated with a hydrophobic biostable elastomeric material (polyurethane) and a biologically active substance (heparin) (see the Abstract and 3:62-4:18). The coating forms a continuous layer that preserves openings 17. The stent may be formed of stainless steel, nitinol or other appropriate metallic alloy (3:62-4:4).

Dayton, as discussed above, discloses the expandable stent for implantation as claimed. Dayton however fails to disclose the specific structure of the stent. It is well known in the art that stents may have various geometries, i.e. parallelograms. With reference to Figure 1 Burton teaches an expandable stent 10 for implantation wherein the openings 22 defined by strands, substantially in the shape of a parallelogram to form a stent with geometry that allows it to expand by itself from a radially compressed

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condition to a larger diameter that exerts an outward force against the vessel wall to maintain the stent in place (1:5-15, 3: and 2:34-47).

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the stent as disclosed by Dayton in order to produce a stent that is capable of expanding by itself from a radially compressed condition to a larger diameter that contacts the vessel walls and maintains the position of the stent within the patients vasculature.

Claims 2, 4, 7, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Burton and further in view of Berg (5,464,650).

The combination of Dayton and Burton, as discussed above discloses the expandable stent for implantation in a patient as claimed. Dayton however fails to disclose the specific thickness and composition of the coating.

Berg teaches a self-expanding stent having a coating comprised of a polymer, a solvent, and a therapeutic substance with varying concentrations and a thickness in the range of 50 micrometers to 25 micrometers (see Figure 1 and 2:30-67). The method required for coating the device is extremely simple and allows the manufacturer to control the amount of drug applied to the stent (2:30-67). Berg discloses that the polymer and solvent can be combined in concentrations (mg/L) in Figures 1 and 2 so that the ratio of therapeutic substance to polymer in the solution is dependent of the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate

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at which the coating is release the therapeutic substance to the tissue and blood vessel (5:8-19). The coating is applied through immersion of the stent or spray coating it with an airbrush, which requires the rotation of the stent to ensure that all sidewalls of the stent are appropriately coated (4:19-35).

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the expandable stent as disclosed by the combination of Dayton and Burton by incorporating the coating as taught by Berg to provide a coated stent that is easy to produce and allows the producer to control the thickness and amount of drug that is contained in the coating.

Claims 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Burton and further in view of Berg (5,464,650).

Dayton as modified by Burton and further modified by Berg discloses the expandable stent for implantation into a patient as claimed. However, the combination does not disclose expressly a coating having a thickness that is about 75 to 200 micrometers.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to coat the device as disclosed by Dayton and Berg with a coating of a different thickness because Applicant has not disclosed that the specific thickness of 75-200 micrometers provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art,

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furthermore, would have expected Applicant's invention to perform equally well with a coating thickness of 25 to 50 micrometers because this thickness provides the delivery of bioactive substances and maintains a low profile design of the stent. Therefore, it would have been an obvious matter of design choice to modify the combination of Dayton, Burton, and Berg to obtain the invention as specified in claims 5 and 16.

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection. Applicant is encouraged to contact the examiner in view of the new groups of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone  
Examiner  
Art Unit 3738

CDP



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